

### REMARKS/ARGUMENTS

Claims 1 to 27 are pending. Claims 1, 5, 7, 8 and 10 have been amended.

The Abstract Of The Disclosure has been objected to because it is over 15 lines in length and appears to have more than 150 words.

The Office Action stated: that correction is required; and see MPEP § 608.01(b). The Abstract has been amended to be not over 15 lines in length and to contain 150 or less words.

This objection should be withdrawn.

The Office Action stated: that the numbering of the claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution; that, when claims are canceled, the remaining claims must not be renumbered; that when new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not); that there is no Claim 25; and that the claims should be numbered appropriately in the next response.

Page 1 of the Office Action states that Claims 26 to 28 have been objected to. These claims have been renumbered to be Claims 25 to 27.

This objection should be withdrawn.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 8 to 12, 23 and 24 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. Applicants traverse, in part, this rejection.

The Office Action stated that Claim 1 has been rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections.

The Office Action stated to see MPEP § 2172.01.

The Office Action stated that the omitted structural cooperative relationships are: the relationship between the base part, the cover film and the lower sealing tray, and particularly, between the base part and the lower sealing tray, it seems that these two claimed components are different names for the same component of the blister pack. This matter is believed to have been corrected in Claim 1.

The Office Action stated that, furthermore, what is the "rear" of the base part? This matter has been corrected.

The Office Action stated that clarification and/or correction is required. Claim 1 has been corrected.

The Office Action stated that the language of Claim 8 is contradictory to the language of Claim 4 (upon which Claim 8 depends) and Claim 1 because Claim 4 is drawn to the "peelable plastics material coating" embodiment of Claim 1, whereas claim 8 is drawn to a different embodiment. Claim 5 has been made dependent upon Claim 1.

The Office Action stated: that the embodiment recited in Claim 8 cannot be present in Claim 8 since a different embodiment is required in Claim 4; and that correction is required. This matter has been corrected in the claims.

This rejection should be withdrawn.

Claims 9 to 12 have been rejected under 35 U.S.C. 112 for the same reason as Claim 8 due to the dependency of Claims 9 to 12 upon Claim 8. Amendments to make Claims 5, 7, 8 and 10 each dependent upon independent Claim 1 solves these problems.

The Office Action stated that Claims 9 to 12, 23 and 24 must also be corrected

due to similar inconsistencies in language (as in Claim 8): "the lacquer" (Claim 9), "the peelable plastics material film" (Claims 10 and 11), "the plastics material coating" (Claim 12: which depends upon Claim 10, which requires a different embodiment from the "plastics material coating"), "the plastics material film" (claim 23) and "the protective lacquer" (Claim 24). The claim amendment solve these problems.

This rejection should be withdrawn.

The Office Action stated that the following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 13, 14, 16, 19 and 20 have been rejected under 35 U.S.C. 102(b) as being anticipated by Hatakeyama (U.S. Patent No. 6,113,927). Applicants traverse the rejection.

The Office Action has misdescribed the packaging disclosed by Hatakeyama. The Examiner has incorrectly tried to make one element into two elements. There is no anticipation by Hatakeyama.

Hayakeyama discloses a package for packing liquid materials, comprising a container 2 made of, e.g., polyethylene, which is permeable to water and oxygen. Container 2 is filled with an aqueous liquid material 1 and is then sealed. As can be seen from Figures 4 to 6, container 2 is packed in a blister pack, which is then closed by sealing the lid 32 (cover film) onto the blister pack 31 (blister base part). The nomenclature used for the same parts in the present invention are put in parentheses.

From Figure 5 (of Hatekeyama) it is clear that the container 2, filled with the

aqueous liquid material, is neither connected to the blister pack (blister base part) 31 nor connected to the lid (cover film) 32. The container 2, filled with aqueous liquid material 1, is packed in the blister pack the same way as a tablet or a capsule containing a drug is packed in a well-known blister pack for pharmaceutical. There is no anticipation by Hatekeyama.

The purpose of the blister pack of Hatekeyama is to protect the aqueous liquid material 1 filled in the sealed container 2, made of a low cost noncarrier material, such as, polyethylene, against reactions with oxygen. As shown in Figure 6, this object is achieved with a blister base part made of a three-layer laminate having good barrier properties against the passage of oxygen, e.g., a laminate PP (38) / EVOH (39) / PP (38). The lid material is a laminate consisting, from the interior to the exterior side, of a sealable layer of LDPE (40), an oxygen absorbing layer (33), a layer of EVOH/LDPE (34), an aluminum foil (37) and a PET-film (35) with a print (38) on its backside. After the container 2 is filled into the blister base part 31, the blister base part 31 is closed by the sealing lid 32 to the peripheral rim of the base part 31. Oxygen which is within the blister pack is removed with the aid of the oxygen absorbent layer 33 within the lid material 32.

#### The blister pack according to the present invention

A blister pack as that shown in Figure 5 of Hatakeyama is also part of the present invention. The major difference between the blister pack as shown in Figure 5 of Hatakeyama and the blister pack according to the present invention as shown in Figure 1 of the present application is the arrangement of a further film in the form of a lower sealing tray 18 extending over the blister base part 12 and sealed against a peripheral edge 20 of the blister base part 12 so as to be peelable.

The side of the blister base part 12 with the openings of the individual blisters or cups 14 formed from the blister base part 12 to received a pharmaceutical filling, such

as, tablets or capsules, is named the front (or front side) of blister based part 12, and the side with cups 14 is the rear (or rear side) of blister base part 12. Consequently, the lid material or cover film 16 is always sealed against the front of blister base part 12, and, therefore, the lower sealing tray 18, extending over the formed cups 14, is sealed against the rear of blister base part 12.

In the light of the above it is clear that the blister pack of Hatakeyama is quite different from the blister pack according to the present invention in that the real (or major) inventive feature, namely, the lower sealing tray 18, is not part of the blister pack of Hatakeyama. In fact, Hatakeyama does not anticipate any of applicants' claims.

The present invention starts from a blister pack known under the term "tropical blister" of a thermoformed blister base part, a cover film of aluminum or an aluminum/plastics material composite, and a lower sealing tray, which is cold-formed from an aluminum/plastics material laminate and is sealed against the rear of the blister base part. Therefore, in a tropical blister, the blister base part with the filling is completely protected by the aluminum films in the cover layer and in the lower sealing tray against the penetration of steam and gases from the external atmosphere. In the tropical blisters known today, the lower sealing tray is firmly sealed against the base part. The filling is pressed through the cover film by pressure on the aluminum/plastics material laminate and the thermoformed cup of the base part located below it. As neither the filling nor the individual cup is visible from outside, there are problems in pressing out the filling.

The purpose of the present invention is to provide a tropical blister as mentioned above, in which the filling is visible prior to removal and, therefore, can be pressed through the cover film without damaging adjacent regions. This object is achieved in that the lower sealing tray 18 is peelably sealed against a peripheral edge 20 of the blister base part 12.

The Office Action stated that, in regard to Claim 1, Hatakeyama teaches a blister pack comprising (1) a blister base part comprising a plastics material (see, for example, col. 9, lines 1 to 26, col. 7, lines 6 to 11 and lines 17 to 24, and col. 2, lines 49 to 62), (2) a cover film comprising an aluminum/plastics material composite (see, for example, col. 9, lines 1 to 15), and (3) a lower sealing tray comprising an aluminum/plastics material composite (see, for example, col. 9, lines 1 to 26, col. 7, lines 6 to 11 and lines 17 to 24, col. 6, lines 36 to 44, and col. 2, lines 49 to 62) that is in contact with and/or comprises a peelable plastics film having a thickness between 10 and 40 microns (for example, sealant layer having a thickness of 30 microns, col. 9, lines 1 to 8). Applicants traverse this statement as a misdescription of the disclosure of Hatakeyama. Column 7, lines 6 and 7, of Hatakeyama deals with its "outer packaging contains". Column 7, lines 17 to 24, set out "sealable container" examples of such outer packaging containers. Such sealable container has only two parts, that is, a molded container and lid member. (See Figures 4 to 6 of Hatakeyama.) The Examiner incorrectly describes as having three elements in its outer packaging container. Hatakeyama is not anticipatory.

The Office Action stated that, in regard to Claim 3, Hatakeyama teaches that the peelable plastics film has a thickness between 15 and 30 microns (for example, sealant layer having a thickness of 30 microns, col. 9, lines 1 to 8). The independent claim is not anticipated, so the dependent claim is not anticipated.

The Office Action stated that, in regard to Claim 14, the plastics material of the blister base part of Hatakeyama has "a barrier with a penetration barrier effect against steam and/or gases" because it is formed from a continuous film of plastics material (i.e. a film that is not perforated: any sheet of plastics material has some degree of penetration barrier effect against steam and/or gases"). The independent claim is not anticipated, so the dependent claim is not anticipated.

The Office Action stated that, in regard to Claim 16, the aluminum/plastics material composite film comprises an aluminum film having a thickness of 20 microns and a PET film having a thickness of 12 In regard to Claim 19, Hatakeyama teaches that the peelable plastics film comprises a microns (see, for example, col. 9, lines 1 to 26, col. 7, lines 6 to 11 and lines 17 to 24, col. 6, lines 36 to 44 and col. 2, lines 49 to 62). polyethylene (see, for example, col. 9, lines 1 to 13). The independent claim is not anticipated, so the dependent claim is not anticipated.

The Office Action stated that in regard to Claim 20, Hatakeyama teaches that the peelable plastics film is co extruded with the other layers of the laminate (see, for example, col. 9, lines 1 to 26). The independent claim is not anticipated, so the dependent claim is not anticipated.

This rejection should be withdrawn.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The Office Action stated that the factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

In neither of the obviousness rejections has the Examiner factually determined, as is mandatory, the level of ordinary skill in the pertinent art. Since this factual inquiry is missing, both obviousness rejections are faulty and fail. Applicants request withdrawal of both failed obviousness rejections and allowance of the claims or a new non-final Office Action that complies with stated Patent Office policy and the pertinent Supreme Court decisions.

Claims 1, 2, 4 to 12, 15 to 17, 19 to 24 and 26 to 28 (correctly numbered Claims 25 to 27) have been rejected under 35 U.S.C. 103(a) as being unpatentable over Hatakeyama (U.S. Patent No. 6,113,927). Applicants traverse this rejection.

The content of Hatakeyama has been set out above. Hatakeyama does not teach or suggest applicants' claimed invention to one ordinarily skilled in the art. The Examiner has not factually or legally shown that applicants' claimed invention is obvious over Hatakeyama to one ordinarily skilled in the art.

The major difference between the blister pack as shown in Figure 5 of Hatakeyama and the blister pack according to the present invention as shown in Figure 1 of the present application is the arrangement of a further film in the form of a lower sealing tray 18 extending over the blister base part 12 and sealed against a peripheral edge 20 of the blister base part 12 so as to be peelable. This packaging is not obvious to one ordinarily skilled in the art.

The side of the blister part 12 with the openings of the individual blisters or cups 14 formed from the blister base part 12 to receive a pharmaceutical filling, such tablets or capsules, is named the front (or front side) of blister base part 12, and the side with



cups 14 is the rear (or rear side) of blister base part 12. Consequently, the lid material or cover film 16 is always sealed against the front of blister base part 12, and, therefore, the lower sealing tray 18, extending over the formed cups 14 is sealed against the rear of blister base part 12.

In the light of the above it is clear that the blister pack of Hatakeyama is very different from the blister pack according to the present invention in that the real or major inventive feature, namely, the lower sealing tray 18, is not part of the blister pack of Hatakeyama. The result is that Hatakeyama directs away from applicants' claimed invention and makes it unobvious to one ordinarily skilled in the art.

The present invention starts from a blister pack known under the term "tropical blister" of a thermoformed blister base part, a cover film of aluminum or an aluminum/plastics material composite, and a lower sealing tray, which is cold-formed from an aluminum/plastics material laminate and is sealed against the rear of the blister base part. Therefore, in a tropical blister, the blister base part with the filling is completely protected by the aluminum films in the cover layer and in the lower sealing tray against the penetration of steam and gases from the external atmosphere. In the tropical blisters known today, the lower sealing tray is firmly sealed against the base part. The filling is pressed through the cover film by pressure on the aluminum/plastics material laminate and the thermoformed cup of the base part located below it. As neither the filling nor the individual cup is visible from outside, there are problems in pressing out the filling.

The purpose of the present invention is to provide a tropical blister as mentioned above, in which the filling is visible prior to removal and, therefore, can be pressed through the cover film without damaging adjacent regions. This object is achieved in that the lower sealing tray 18 is peelably sealed against a peripheral edge 20 of the blister base part 12. Applicants' claimed invention is unobvious to one ordinarily skilled

in the art.

Applicants have shown the unexpected advantage of their claimed invention that shows the unobviousness thereof over Hatakeyama to one ordinarily skilled in the art.

The Office Action stated that, in regard to Claims 1, 2, 16 and 28 (now 27), Hatakeyama teaches a blister pack comprising (1) a blister base part comprising a plastics material (see, for example, col. 9, lines 1 to 26, col. 7, lines 6 to 11 and lines 17 to 24, and col. 2, lines 49 to 62), (2) a cover film comprising an aluminum/plastics material composite (see, for example, col. 9, lines 1 to 15), and (3) a lower sealing tray comprising an aluminum/plastics material composite (see, for example, col. 9, lines 1 to 26, col. 7, lines 6 to 11 and lines 17 to 24, col. 6, lines 36 to 44 and col. 2, lines 49 to 62) that is in contact with and/or comprises a peelable heat-sealing layer (for example, sealant layer having a thickness of 30 microns, col. 9, lines 1 to 8, where the sealant corresponds to the claimed lacquer). This statement is factually incorrect, as shown above.

The Supreme Court's Graham decision requires the mandatory determination of three factual inquiries before any decision of obviousness can be made. These mandatory factual determinations, identification their factual basis, and supporting reasons and facts have to be of record in this the "written" [electronic] record of this application (required by Patent Office rules). The record of this application does not contain resolution of at least one of such mandatory determinations, identification the supporting facts, etc., therefore, the Section 103(a) rejection is fatally defective. Applicants request that the claims be allowed or that a non-final Office Action that has a correct obviousness rejection be issued.

In the record of this application there is no resolution of the level of ordinary skill in the pertinent art (this is a mandatory factual determination) or indication of the supporting facts. In fact, in the obviousness rejection in the Office Action there is no mention of one ordinarily skilled

in the art. The Section 103(a) rejection fails because the Examiner has not built the mandatory factual determinations and foundation required before any decision of obviousness can be made. The Examiner has not complied with the requirements of the Supreme Court's Graham decision, so he still has the burden of proof. Until he complies with the Graham decision and Patent Office policy, and builds the foundation of mandatory factual determination, the burden stays with him and he cannot try to use the product-by-process approach to try to shift the burden of proof to the applicant. No prima facie showing of obviousness can be established until all of the Graham factual inquiries have been determined in the record.

Patent Office policy is to follow *Graham v John Deere Co.* in the consideration and determination of obviousness under 35 U.S.C. 103(a) [MPEP 2141.1).

In 2007, the Supreme Court's KSR decision affirmed that their Graham decision was still the law on what was required under Section 103(a) In order to make an obviousness decision. The Supreme Court Slated "...., the factors continue to control." The Graham framework or foundation still applies. The Examiner did not comply by factually resolving in the record the level of ordinary skill in the art, so the obviousness rejection fails on its face.

The Examiner has not shown that Hatakeyama teaches or suggests the claimed invention. The result of the Examiner's attempts is still not applicants' claimed invention.

The burden of proof is upon the Examiner and he has not carried his burden.

The Office Action stated that Hatakeyama fails to explicitly teach that the peelable heat-sealing layer is applied at an application weight of 2 to 20 g/m<sup>2</sup> (or 7 to 15 g/m<sup>2</sup> as claimed in Claims 2 and 28, or 1 to 20 g/m<sup>2</sup> as claimed in Claim 16). This not all that Hatakeyama does not teach or suggest.

The Office Action stated that, however, Hatakeyama teaches that the degree of desired peelability and heat sealability should be taken in account when selecting the material of the heat sealing layer (col. 6, lines 26 to 35). This statement is meaningless until the Graham case has been complied with.

The Office Action stated that, therefore, one of ordinary skill in the art would have recognized to have varied the thickness of the heat sealing layer in order to achieve the desired degree of peelability and heat sealability of the heat sealing layer depending on the particular desired end result, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art in the absence of unexpected results. Applicants traverse this statement. The Examiner does not know what one ordinarily skilled in the art would recognize, or anything about such a person. The reason is that the Examiner has not factually determined the level of ordinary skill in the art. The assertion regarding an optimum value is meaningless until the requirements of the Graham decision have been complied with

The Office Action cited *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980), and MPEP 2144.05II.B. These citations are meaningless until the Supreme Court's decisions and Patent Office policy have been complied with.

The Office Action stated that, in regard to Claims 1 and 4, Hatakeyama teaches a blister pack comprising a blister base part comprising a plastics material (see, for example, col. 9, lines 1 to 26, col. 7, lines 6 to 11 and lines 17 to 24, and col. 2, lines 49 to 62), a cover film comprising an aluminum/plastics material composite (see, for example, col. 9, lines 1 to 15) and a lower sealing tray comprising an aluminum/plastics material composite (see, for example, col. 9, lines 1 to 26, col. 7, lines 6 to 11 and lines 17 to 24, col. 6, lines 36 to 44, and col. 2, lines 49 to 62) that is in contact with and/or comprises a peelable plastics material coating (for example, sealant layer having a thickness of 30 microns, col. 9, lines 1 to 8, where the sealant corresponds to the claimed lacquer). This statement is factually incorrect, as shown above.

The Office Action stated that Hatakeyama fails to explicitly teach that the peelable plastics material coating is applied at an application weight of 5 to 40 g/m<sup>2</sup> (or 7 to 20 g/m<sup>2</sup> as claimed in Claim 4). This is not all that Hatakeyama does not teach or suggest.

The Office Action stated that, however, Hatakeyama teaches that the degree of desired peelability and heat sealability should be taken in account when selecting the material of the peelable layer (col. 6, lines 26 to 35). This statement is meaningless until the Graham case has been complied with.

The Office Action stated that, therefore, one of ordinary skill in the art would have recognized to have varied the thickness of the peelable layer in order to achieve the desired degree of peelability and heat sealability of the heat sealing layer depending on the particular desired end result, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art in the absence of unexpected results.

The Office Action cited *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980), and MPEP 2144.05 II.B. These citations are meaningless until the Supreme Court decisions and Patent Office policy have been complied with.

The Office Action stated that, in regard to Claim 5, the plastics material of the blister base part of Hatakeyama has "a barrier with a penetration barrier effect against steam and/or gases" because it is formed from a continuous film of plastics material (i.e., a film that is not perforated: any sheet of plastics material has some degree of "penetration barrier effect against steam and/or gases"). This does not make any of applicants' claims obvious.

The Office Action stated that, in regard to Claims 6 and 15, Hatakeyama teaches that polyvinyl chloride (PVC) and polyolefins are suitable materials for the base sheet (col. 3 lines 10 and 11). This is of little importance because it does not make applicants' inventions as a whole obvious.

The Office Action stated that, in regard to Claim 7, the aluminum/plastics material composite film comprises an aluminum film having a thickness of 20 microns and a PET film having a thickness of 12 microns (see, for example, col. 9, lines 1 to 26, col. 7, lines

6 to 11 and lines 17 to 24, col. 6, lines 36 to 44 and col. 2, lines 49 to 62). This is of little importance because it does not make applicants' inventions as a whole obvious.

The Office Action stated that Claims 8 to 12, 23 and 24 cannot be treated due to the indefiniteness of these claims. Applicants traverse this statement, assert that such claims are understandable enough to have been examined on their merits, and ask for a new nonfinal Office Action be issued (if the claims are not all allowed).

The Office Action referred to the 35 U.S.C. 112 rejection of Claims 8 to 12, 23 and 24 made of record above in the Office Action. The Office Action stated that, if Claims 8 to 12, 23 and 24 are so indefinite that they cannot be treated, then the Examiner cannot determine that such claims are obvious under Section 103(a) (since he does not know what they cover, etc., by his own statement). Therefore, by the Examiner's own statement, the rejection of Claims 8 to 12, 23 and 24 under Section 103(a) is in error. The subject claims were not so indefinite that they could not be examined under Section 103(a). What the real issue is: all of the claims asserted to be obvious by the Examiner have not been shown to be obvious because the Section 103(a) fails as to all of the claims that have been rejected under Section 103(a) since the Examiner has not factually resolved, as is mandatory, in the record the level of ordinary skill in the art.

The Office Action stated that, in regard to Claim 17, Hatakeyama teaches the blister pack as discussed above in regard to Claims 1 and 2. Applicants traverse this statement as being incorrect.

The Office Action stated that Hatakeyama teaches the blister pack as recited in Claim 17 (see, for example, col. 9, lines 1 to 33). This is of little importance because it does not make applicants' inventions as a whole obvious.

The Office Action stated that, in regard to Claim 19, Hatakeyama teaches the blister pack as discussed above in regard to Claims 1 and 5. This is of little importance

because it does not make applicants' inventions as a whole obvious.

The Office Action stated that, Hatakeyama teaches the blister pack as recited in Claim 19 (see, for example, col. 9, lines 1 to 33). This is of little importance because it does not make applicants' inventions as a whole obvious.

The Office Action stated that, in regard to Claims 22 and 26 (now 25), Hatakeyama teaches that the aluminum foil is a barrier layer (col. 6, lines 35 to 44). This is of little importance because it does not make applicants' inventions as a whole obvious.

The Office Action stated that, therefore, one of ordinary skill in the art would have recognized to have varied the thickness of the aluminum foil in order to achieve the desired degree of barrier properties depending on the particular desired end result, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art in the absence of unexpected results. Applicants traverse this statement because that the Examiner cannot make any assertion regarding one ordinarily skilled in the art since the Examiner has not factually determined, as is mandatory, the level of ordinary skill in the art.

The Office Action cited *In re Boesch*, 617 F.2d 272,205 USPQ 215 (CCPA 1980), and MPEP 2144.05 II.B. These citations are meaningless until the Supreme Court decisions and Patent Office policy have been complied with.

The Office Action stated that, in regard to Claim 27 (now 26), Hatakeyama teaches the blister pack as discussed above in regard to Claims 1, 3 and 16. These citations are meaningless until the Supreme Court decisions and Patent Office policy have been complied with.

The Office Action stated that Hatakeyama teaches that the degree of desired peelability and heat sealability should be taken in account when selecting the material of the heat sealing layer (col. 6, lines 26 to 35). These citations are meaningless until the

Supreme Court decisions and Patent Office policy have been complied with.

The Office Action stated that, therefore, one of ordinary skill in the art would have recognized to have varied the thickness of the heat sealing layer in order to achieve the desired degree of peelability and heat sealability of the heat sealing layer depending on the particular desired end result, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art in the absence of unexpected results. Applicants traverse this statement. The Examiner does not know what one ordinarily skilled in the art would recognize, or anything about such a person. The reason is that the Examiner has not factually determined the level of ordinary skill in the art. The assertion regarding an optimum valve is meaningless until the requirements of the Graham decision have been complied with.

The Office Action cited *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980), and MPEP 2144.05 II.B. These citations are meaningless until the Supreme Court decisions and Patent Office policy have been complied with.

This rejection should be withdrawn.

Claim 18 has been rejected under 35 U.S.C. 103(a) as being unpatentable over Hatakeyama (U.S. Patent No.6,113,927) in view of Holbert et al. (U.S. Patent No. 7,192,640). Applicants traverse this rejection.

Holbert does not cure the defects of Hatakeyama in the search for applicants' claimed invention.

The Office Action stated that Hatakeyama teaches the blister pack as discussed above in regard to Claim 17. This is of little importance because it does not make applicants' invention as a whole obvious.

The Office Action stated that Hatakeyama fails to explicitly teach that the heat seal includes any of the materials recited in Claim 18. Hatakeyama fails to disclose several other things.



The Office Action stated Holbert et al., however, disclose a blister package (col. 1, lines 9 to 14) comprising a heat seal polymer, where acrylic copolymers are suitable materials for the material of the heat seal (see, for example, col. 2, lines 59 to 64). Applicants traverse this statement. Col. 1, lines 9 to 14, deals with prior art and does not recite "heat seal" polymer.

The Office Action stated that, therefore, one of ordinary skill in the art would have recognized to have used an acrylic heat seal copolymer as the material of the heat seal polymer of Hatakeyama since acrylic copolymers well known to be suitable materials for the material of the heat seal of blister packages as taught by Holbert et al. Applicants traverse this statement. The Examiner does not know what one ordinarily skilled in the art would recognize, or anything about such a person. The reason is that the Examiner has not factually determined the level of ordinary skill in the art. The assertion regarding an optimum valve is meaningless until the requirements of the Graham decision have been complied with.

The Office Action stated that, furthermore, selection of a particular material that was known prior to the invention as the material for use in the invention has been held to be obvious. This statement is of no importance under Section 103(a) in the case at bar because Supreme Court decisions control.

The Office Action stated see MPEP 2144.07. The M.P.E.P. fails when Patent Office policy has not been complied with and Supreme Court decisions are involved.

The Office Action stated that it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used an acrylic heat seal copolymer as the material of the heat seal polymer of Hatakeyama since acrylic copolymers well known to be suitable materials for the material of the heat seal of blister packages as taught by Holbert et al. The Examiner does not know what would be obvious to one

ordinarily skilled in the art (because he has not factually determined the level of ordinary skill in the art).

This rejection should be withdrawn.

Reconsideration, reexamination and allowance of the claims are requested.

Respectfully submitted,

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<p align="center"><b>CERTIFICATE OF MAILING</b></p> <p>I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on <u>August 8, 2008.</u></p> <p align="right"><u>Virgil H. Marsh</u> FISHER, CHRISTEN &amp; SABOL 1120 20<sup>th</sup> Street, N.W. South Tower, Suite 750 Washington, D.C. 20036</p>
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## **APPENDIX**